

OCT 10 2008

K082653

510(k) Summary

The information below is provided for the Modifications to the Centering Intraluminal Applicators, following the format of 21 CFR 807.92..

Submitter: Varian Medical Systems
3100 Hansen Way M/S E-110
Palo Alto, CA 94304-1129
Contact Name: Ms. Vy Tran
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Fax: (650) 842-5040
Email: vy.tran@varian.com
Date summary was prepared: September 11, 2008

Name of the Device:	Centering Intraluminal Applicator
Trade/Proprietary Name:	Centering Intraluminal Applicator
Common or Usual Name:	Centering Intraluminal Applicator
Classification Name:	System, Applicator, Radionuclide, Remote – Controlled 21 CFR 892.5700 Class II Product Code: JAQ

Predicate Device to claim substantial equivalence:
K983436 – GammaMed Plus High Dose Rate Remote Afterloading System

Description of the Device:

Varian's High Dose Rate BrachyTherapy Afterloaders use a single radioactive source of Iridium-192 to treat cancer in a wide range of body sites.
The radioactive source is enclosed within a wire/cable which is driven via coupling catheters / Transfer Guide Tubes / Source Guide Tubes from the Applicator in to the patient.

Intended Use Statement:

The intended use of the Varian transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation.

Summary of the Technological Characteristics:

The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate device. The chart is located in Tab 7 of this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 10 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Vy Tran
Senior Director, Corporate Regulatory Affairs
Varian Medical Systems, Incorporated
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K082653
Trade/Device Name: Centering Intraluminal Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 11, 2008
Received: September 12, 2008

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

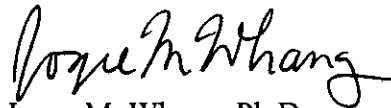
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K082653

Device Name: Centering Intraluminal Applicator

Indications For Use:

The indications for use of the Varian transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Anna M. Whay
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082653